UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	Case No. 1:17-md-2804 Judge Dan Aaron Polster

STATUS REPORT OF THE MYLAN DEFENDANTS

In accordance with this Court's April 21, 2022 Order setting a status conference for certain defendants not previously involved in MDL bellwether tracks, Dkt. No. 4380, the Mylan Defendants ("Mylan")[1] hereby submit their status report. Mylan appreciates the opportunity to update the Court about its status in the MDL and to provide input about next steps relating to the remaining Manufacturers and Distributors.

Mylan is a small participant in the opioid market that has been named as a defendant in the MDL almost entirely on the basis of incorrect market share calculations relating to its generic opioid medications. As the Court is aware, Plaintiffs were allowed in 2018 to name as defendants any opioid manufacturers with at least 5% market share in the ARCOS data. But rather than limiting themselves to the Court's order to calculate market share based on ARCOS data (i.e., by volume), Plaintiffs created a market share metric by adding to the ARCOS data an external calculation of supposed "morphine milligram equivalents" ("MMEs"). Plaintiffs then did not even calculate MME in accordance with the very guidelines they claimed to apply: to calculate the putative MME for fentanyl patches, for example, Plaintiffs used a multiplier nearly 13 times higher

[1] References to Mylan include references to all entities in Mylan's "Defendant Family" that are named in MDL cases. *Id*. Each Mylan Defendant expressly preserves and does not waive all of its individual rights, reservations, objections, and arguments, including with respect to service.

than they said they did (100 rather than the cited factor of 7.2). Relying on this improper MME metric, Plaintiffs asserted that Mylan exceeded the 5% market share threshold the Court established for adding defendants—even as market share calculations by dosage units (volume) show that Mylan did not. In fact, based on Mylan's review of the ARCOS data, Mylan did not have 5% total market share by volume in *any* of the county lawsuits in which it is named.

As a result, Mylan respectfully is not in a position to meaningfully evaluate the Court's inquiry about settlement negotiations or bellwether tracks at this time, including how any such negotiations or tracks should proceed. More information is needed from Plaintiffs to enable the parties and the Court to understand whether the cases filed against Mylan pursuant to the Court's 5% market share order have been permissibly asserted. Mylan thus requests that the Court direct Plaintiffs to undertake—on short order—the specific steps set forth in Section II of this status report to "clean up" their cases against Mylan and the other remaining Defendants by addressing both MME market share concerns and other issues regarding filing, service, and fact sheets. Mylan further suggests that, following that effort, the Court and the parties reconvene to determine how best to proceed with these cases. In the meantime and absent such an effort, Mylan submits that further proceedings would be premature and would suffer from a lack of clarity on these issues.

I. Background on Mylan's Status in the MDL

A. Plaintiffs Name Mylan on the Basis of An Improper MME Metric.

In November 2018, the Court ordered the Plaintiffs' Executive Committee to submit reports reflecting the names of all labelers (as identified by NDC code) who manufactured and/or labeled more than five percent of the market share of opioids distributed in the relevant county or county-equivalent in at least three of the nine years available in ARCOS data. *See* Nov. 8, 2018 Order Regarding Plaintiff's Motion for Modification of CMO-1, Dkt. No. 1106 (hereinafter "2018

Order"). The 2018 Order did not define the basis by which Plaintiffs could or should measure "market share of opioids," but specified that Plaintiffs must do so through the ARCOS data. *Id.* The 2018 Order further allowed Plaintiffs to amend complaints on the basis of these market share reports via a "short form" complaint by March 16, 2019 (or, for new complaints, 90 days following transfer to the MDL).[2] 2018 Order at 3; *id.* at 3 n.7.

Thereafter, at the Court's direction, Plaintiffs, through Dr. Craig McCann of SLCG Economic Consulting, made purported market share reports publicly available to every county across the country. *See Opioid Data,* slcg Economic Consulting, https://www.slcg.com/opioid-data/ (last visited June 15, 2022). Critically, the reports offer two different measures of putative market share calculations: (1) by "dosage units" (i.e., volume), which is a traditional commercial means of measuring market share based on data contained within ARCOS; and (2) by supposed MMEs, which is one clinical tool employed by practitioners when comparing opioid dosing for individual patients—not a parameter tracked by ARCOS. *See, e.g.*, Grace Chai, *Morphine Milligram Equivalents (MMEs),* U.S. Food and Drug Administration (June 7-8, 2021), https://www.fda.gov/media/150436/download (explaining that MMEs "assist clinicians in determining [an] initial dose when converting an individual patient's opioid therapy" while accounting for differences in opioid drug type and strength).

Plaintiffs' improper use and calculation of the so-called MME measure is responsible for the extent of Mylan's lawsuits. Based on Mylan's review of the ARCOS data, the many cases in which Mylan is named on the putative basis of ARCOS data—and which make no substantive

[2] Many Plaintiffs have been filing ever since, as recently as May 9, 2022, on the putative basis of their review of ARCOS data. *See, e.g.*, Short Form Complaint at 2-3, *City of Childersburg, Alabama v. AmerisourceBergen Drug Corp.*, Case No. 1:22-op-45020 (N.D. Ohio filed May 9, 2022), Dkt. No. 11 (naming Mylan Pharmaceuticals Inc. and certifying that "in identifying all Defendants, I have followed the procedure approved by the Court and reviewed the ARCOS data that I understand to be relevant to Plaintiff(s)" and explaining "each of the Defendant(s) newly added herein appears in the ARCOS data I reviewed").

allegations of wrongdoing by Mylan—are dependent solely on Plaintiffs' MME calculations. This distorted view of Mylan's role should be corrected before the Court and the parties can assess the best approach for advancing and resolving these cases.

B. Plaintiffs' MME Market Share Analysis Conflicts with the Court's Order and Is Incorrect.

There are two primary reasons why Plaintiffs' MME market share calculations create threshold issues for moving forward as to Mylan's cases in the MDL.

First, reliance on MMEs to assess market share does not comport with the Court's 2018 Order, which allowed Plaintiffs to file complaints based on ARCOS data. *See* 2018 Order. The ARCOS data does not include MMEs in any form; DEA registrants do not report MMEs to DEA, and DEA does not calculate them. *See, e.g.*, 21 CFR § 1304.33 (requiring data on "each acquisition to inventory . . . and each reduction from inventory" that identifies "the particular form, strength, and trade name"). Indeed, Dr. McCann has acknowledged that he had to "*add* [an] MME conversion factor to the ARCOS Data." Expert Report of Craig J. McCann, Ph.D., Dkt. No. 1999-13 at 49 (Mar. 25, 2019) (hereinafter "McCann Report") (emphasis added).[3] By Dr. McCann's own admission, Plaintiffs thus did not calculate market share based on objective ARCOS data as directed by the Court's 2018 Order; they *converted* ARCOS data into an external (clinical, nuanced, and contested) measure of potency as an improper means of increasing the number of potential Defendants—without further pre-suit inquiry into whether those Defendants engaged in any allegedly wrongful conduct or caused any injury.

Second, not only did Plaintiffs convert the ARCOS data, they did it incorrectly, even according to their own approach. Take, for example, the manner in which Plaintiffs relied on the

[3] *See also id.* at 48 (stating that he "[s]upplement[ed] the data" by "add[ing] several fields to the ARCOS Data to assist in [his] analysis," including "drug potency information from the CDC's Morphine Milligram Equivalents (MME) conversion table").

MME conversion factor for fentanyl patches, which has had an outsized impact on Mylan. Dr. McCann reported that he used the CDC's MME conversion factor of 7.2, McCann Report at 3, 48,[4] i.e., that a fentanyl patch worn for three days is 7.2 times more potent than morphine.[5] But the spreadsheets that Dr. McCann offered with his reports show that he actually used an MME conversion factor of ***100***, not 7.2. *See* Exhibit 1 (excerpt from Schley County, Georgia SLCG Processed ARCOS Data, showing an "MME conversion factor" of 100 for fentanyl patches) (highlighting added). Dr. McCann then used that overstated conversion factor to estimate market share by MME in every jurisdiction in the United States.

Mylan, one of the manufacturers of a fentanyl patch, has been disproportionately affected by this mistake. Mylan has been repeatedly named as a defendant in the MDL through either the short-form complaint or new complaints with boilerplate representations about reliance on ARCOS data ***even though it does not, in fact, have 5% market share based on ARCOS data***. The market share reports offered by Plaintiffs demonstrate consistently that Mylan had a *de minimis* share of the market by volume of dosage units and did not have 5% market share by any measure

[4] Even Dr. McCann's claimed reliance on the CDC guidelines was not an objective market calculation based on ARCOS data, but rather a subjective assumption. There are numerous MME calculators and tables available, in addition to product package inserts. *See, e.g.* Amanda Rennick et al., *Variability in Opioid Equivalence Calculations*, Pain Med. (May 2016), https://academic.oup.com/painmedicine/article/17/5/892/1752519 (explaining "[t]here is no universally accepted opioid conversion method" and "there is often significant variability between conversion resources"). Further, MME conversion factors are not static. They are often presented in ranges and their application relies, in practice, on clinicians' knowledge of patient-specific factors. *See, e.g.*, DailyMed, *Label: Fentanyl Patch*, NIH U.S. National Library of Medicine, https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2a2238e9-4b5d-c56d-8663-dd354ff9ae0c (listing dose conversions for "Fentanyl Transdermal System" in ranges of daily morphine doses) (last updated March 25, 2021). Mylan reserves all rights to challenge how Dr. McCann processed the ARCOS data, any expert opinions related to ARCOS data or MMEs, and whether ARCOS data or MMEs can properly be used to measure market share.

[5] McCann Report App'x 8 ("MME Conversion Factors (from CDC)") (listing the MME Conversion Factor for fentanyl patch as 7.2); *id.* n.1 (instructing that to calculate daily MME, the conversion factor "is to be used in the formula: Strength per Unit X (Number of Units/Days Supply) X MME conversion factor = MME/Day," such as 12.5 x (1/3) x 7.2 = 30). However, Mylan does not concede that even a 7.2 conversion factor is appropriate. Moreover, the CDC MME conversion factors that Dr. McCann claims to have relied upon have since been clarified with respect to fentanyl patches. *MME for Commonly Prescribed Opioids*, Centers for Disease Control and Prevention, https://www.cdc.gov/opioids/providers/prescribing/guideline.html#anchor_1561563251 (listing factor for "fentanyl transdermal" as ***2.4***) (last visited June 15, 2022).

other than MME. *See, e.g.*, Exhibit 2 (SLCG report for Schley County, Georgia, listing Mylan Pharmaceuticals Inc. as having 6.1% of the market share by MME but only 0.1% by total dosage units); Exhibit 3 (SLCG report for Bayfield County, Wisconsin, listing Mylan Pharmaceuticals Inc. as having 16.3% of the market share by MME but only 0.7% by total dosage units); Exhibit 4 (SLCG report for Ogemaw County, Michigan, listing Mylan Pharmaceuticals Inc. as having 21.9% of the market share by MME but only 1.1% by total dosage units). In fact, based on Mylan's review of the ARCOS data, Mylan does not have 5% total market share by volume (across all opioid products) in any of the county lawsuits in which it is named.[6]

Mylan thus should not have been named as a defendant under the standards in the Court's 2018 Order. And to be clear, this is not a "battle of the experts" to be sorted out in litigation. It is a fundamental gating issue for Mylan's future progression in the MDL, because Mylan's entire scope of MDL litigation in the current environment is wrong. The universe of cases against Mylan cannot be properly assessed because of Plaintiffs' unsupported use of MMEs to convert market share and their reliance on an erroneous MME conversion factor for fentanyl patches.

II. Proposed Next Steps

It is against this backdrop that Mylan offers its response to the Court's request for positions regarding next steps, including as to settlement negotiations or bellwether cases, if any.

[6] Mylan strongly disagrees with the concept of using MMEs to calculate market share and reserves its objections to Dr. McCann's stated methodology. However, even if Dr. McCann had used the 7.2 conversion factor he claimed to use for fentanyl patches—rather than 100—Mylan believes it would still only surpass the 5% market share threshold by MME in a *handful* of cases. Moreover, Mylan has been baselessly named in many suits in which its market share is well below 5% by "dosage units" *and* below 5% even using Plaintiffs' incorrect MME calculation. *See, e.g.*, Exhibit 5 (SLCG report for Butler County, Ohio, listing Mylan Pharmaceuticals Inc. as having only 4.3% of the market share by Plaintiffs' MME calculation from 2006-2014 and only 0.4% by total dosage units).

A. Plaintiffs Should Be Required to Evaluate Their Cases Against the Remaining Defendants in the Next 60 Days Before Further Proceedings Can Occur.

Mylan respectfully submits that further proceedings—whether through negotiation or a bellwether selection process—would be premature until Plaintiffs first address certain threshold issues to allow the parties to evaluate the actual universe of cases pending against the remaining Defendants. Much like the Court acknowledged during the May 23, 2022 status conference, Mylan has no idea "whether or how serious" Plaintiffs are in pursuing their cases against Mylan. As set forth above, the vast majority of cases naming Mylan depend upon check-the-box or formulaic representations about market share that are demonstrably inaccurate, and do not include any allegations of wrongdoing by Mylan.

There are other problems too. For example, many Plaintiffs belatedly filed their amended complaints after the Court's March 16, 2019 deadline. *See, e.g.*, *Butler Cnty. Bd. of Comm'rs v. Purdue Pharma L.P. et al*, No. 1:18-op-45037 (N.D. Ohio Jan. 16, 2018) (transferred on January 16, 2018 and untimely amended via short-form complaint on March 18, 2019). In addition, many Plaintiffs have not even effectuated service (or sought waiver of service) of their Complaints.[7]

Further, Mylan lacks information about the Plaintiffs to which it is entitled under the Court's orders. The Court's June 19, 2018 Fact Sheet Implementation Order, Dkt. No. 638, required all MDL plaintiffs to provide defendants' liaison counsel with a completed Plaintiff Fact Sheet either within 90 days of the date of that order or within 90 days of their case being docketed in the MDL. Yet, Mylan has not received fact sheets for over 50% of the cases in which it has been named. Mylan and other similarly situated defendants, many of which are also late entrants into the MDL, cannot be expected to engage in meaningful settlement negotiations or to discuss a

[7] Mylan has not been served in approximately 40% of the cases pending against it in the MDL—including many cases first filed over three years ago.

bellwether track when they have received virtually no factual information about the cases pending against them and where Plaintiffs have not yet met their own obligations.

Accordingly, Mylan requests that the Court require Plaintiffs to do the following as a threshold matter within 60 days:

1. Determine which defendants manufactured more than 5% market share based on dosage unit information present in the ARCOS data (as the Court has already ordered), and dismiss defendants who do not meet that threshold established by the Court[8];

2. Dismiss as untimely amended complaints that did not meet the Court's amended complaint deadline for filing lawsuits based on ARCOS data;

3. Dismiss any cases or Defendants that were not served within the timeframes set forth in Federal Rule of Civil Procedure 4(m) for failure to effectuate timely service; and

4. Require all Plaintiffs to provide fact sheets to the remaining Defendants or dismiss claims brought by those Plaintiffs.

B. After the MDL Cases Have Been Cleaned Up, the Court Should Reconvene a Status Conference to Discuss Next Steps.

After Plaintiffs' cases have been vetted accordingly, the parties will be better positioned to determine whether settlement negotiations or bellwether selection would be the proper process. Mylan thus proposes that, once Plaintiffs effectuate the measures described above within 60 days, the parties should have 21 days thereafter in which to file updated status reports, and the Court should then reconvene a status conference on or after September 22, 2022 to discuss next steps.

[8] This Court has directed similar actions in the past to clean up the MDL docket, particularly prior to bellwether selection. *See* Order of April 9, 2021, Dkt. No. 3688 at 2 (directing that Pharmacy Defendants "identify for plaintiffs those cases where they have zero-percent market share in the relevant jurisdictions" and that Plaintiffs "begin dismissal of those Defendants with prejudice"). *See also* Order of March 12, 2019, Dkt. No. 1429 at 2 ("The parties and the Court contemplated that Plaintiffs would not only add, *but also remove* defendants based on Plaintiffs' analysis of the ARCOS data.") (emphasis added)); 2018 Order (noting that, as to city plaintiffs, county-level reports could serve as a "reasonable approximation" to identify "appropriately named defendants" but that "necessary corrections—including altering defendants plead by a city" can be made at a later time, particularly if active litigation is contemplated); Ongoing Common Benefit Fund Order of May 9, 2022, Dkt. No. 4428 at 10 (referring to the role of the ARCOS database in "correctly identify[ing] defendants, fil[ing] and amend[ing] complaints"). In the alternative, Mylan asks for an opportunity to formally challenge and brief this cross-cutting MME issue prior to additional proceedings.

Mylan respectfully submits that engaging in a settlement process now would be premature and wasteful in light of the issues discussed above. The extent to which a settlement approach is appropriate will depend on resolving the threshold issues Mylan has identified, and the Court and the parties reaching a common understanding about the universe of cases that remain.

Similarly, as for bellwether selection, Mylan does not believe a bellwether track is necessary or appropriate as to the remaining Defendants. Until Plaintiffs address the various preliminary issues discussed above, Mylan does not know which cases even meet the Court's 5% market share order or are otherwise credibly pending against it, or which other defendants will remain. Mylan therefore also requests that the Court defer any consideration of bellwether selection until at least the next status conference, at which point the Court and the parties will have a better picture of the remaining landscape in the MDL.[9]

Dated: June 16, 2022

Respectfully submitted,

/s/ Rebecca C. Mandel

Adam K. Levin
Rebecca C. Mandel
HOGAN LOVELLS US LLP
555 13th St. NW
Washington, DC 20004
Telephone: (202) 637-5600
Facsimile: (202) 637-5910
adam.levin@hoganlovells.com
rebecca.mandel@hoganlovells.com

Counsel for the Mylan Defendants

[9] Even if the Court were inclined to consider a bellwether, it should at least first establish a process that allows for meaningful evaluation, with input from all parties, of bellwether case candidates. As the Court recently noted at the May status conference, bellwether selection should occur only pursuant to a thorough process.

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was electronically filed and served upon counsel of record by operation of the Court's CM/ECF System on June 16, 2022.

/s/ Rebecca C. Mandel

Counsel for the Mylan Defendants